

combinations of the Burnside or Koblish patents together with U.S. Patent No. 5,680,860 Imran.

More specifically, with respect to claim 1, the Office Action particularly stated that the Burnside '281 patent showed, in Figure 80, jaws members with convex opposed mating surfaces. It is unclear how the Examiner was construing Figure 80 of the Burnside patent to conclude that it disclosed convex opposed mating surfaces on the jaws, but Applicant has further amended the claims to make it clear that the mating surfaces referred to in the claims are the facing mating surfaces of the jaws and not a lateral or side surface of the jaws.

As now amended, claim 1 specifically calls for the jaws to have opposed "and facing" mating surfaces. Each jaw has an elongated "electrically conductive ablation member" (which has been substituted for a prior term "electrode") extending along a central peak on each mating surface of each jaw. Such a feature may be seen in several of the figures of the present application. For example, such a configuration may be seen in Figure 2, Figure 32, Figures 38 and 39, and Figures 41-51.

In contrast, U.S. Patent No. 6,071,281 to Burnside, does not teach or suggest such convex, opposed and facing mating surfaces. Figure 79 of the '281 patent is a cross-sectional view of a clamp jaw, taken along line 79-79 in Figure 78. As can be seen in Figure 79, the facing surfaces of the jaws are not convex with a central

peak, but flat. The convex part of the jaw shown Figure 79 is "outer" surface of the jaw, and not the facing mating surfaces of the jaws which come together when the jaws are closed. Figure 80 shows that the jaws have a slight lateral curvature, but this is a view looking down on the jaws, and it does not show any curvature of the facing mating surfaces of the jaws.

It should also be noted that the '281 Burnside patent does not teach or suggest a thermocouple on a jaw to measure the temperature of tissue clamped between the jaws. Burnside, in contrast to the device of claim 1, is used for cauterizing and sealing tissue together. The Burnside device is therefore intended to provide a wide thermal spread to coagulate the tissue. Sensing the temperature to limit thermal spread when lines of ablation (lesions) are formed, without sealing tissue together, is not disclosed or even consistent with Burnside -- where the object is to maximize thermal effect over a wide area to seal tissue together.

It is therefore clear that the '281 Burnside patent does not disclose or suggest the claimed features as set forth in claim 1, particularly as clarified by this Amendment. For these reasons, it is respectfully submitted that claim 1 and its respective dependent claims should be allowed.

Turning to independent claim 4, in the Office Action claim 4 was rejected as anticipated by the device shown in U.S. Patent No.

6,464,700 to Koblish. (Attention was directed to Figure 21 of Koblish.) The device shown in Koblish, however, is not a tissue grasping apparatus of the type set forth in claim 4, which is intended to clamp tissue between the jaws, with the jaws being substantially parallel when in the closed position to clamp the tissue therebetween. In Koblish, the jaws are shaped to conform to the shape of the structure which they surround. So, for example, as can be seen in Figure 21, the jaws, when closed, define a large aperture to form a continuous loop about a vessel or other body structure enclosed by the clamp "without collapsing the body structure as would be the case with the device having straight arm(s)" (Col. 17, lines 40-45).

The claimed invention employs the very clamp arm structure which the Koblish patent seeks to distinguish. In claim 4, as amended, it is clear that the grasping jaws are moveable to a closed position in which the jaws are substantially parallel, in order to compress tissue therebetween. As described in the specification, this allows the jaws to clamp together opposed organ or vessel walls, for example opposed walls of the atrium, so that a transmural ablation line may be formed through both walls simultaneously when they are clamped together in a compressed position between the facing surfaces of the jaws and the electrodes are energized. The clamp shown in the '700 Koblish patent operates on an entirely different and opposite principle.

Additionally, Koblish does not disclose a thermocouple to sense the temperature of tissue compressed between the jaws. First, Koblish does not compress tissue between the jaws as discussed above. Second, Koblish controls temperature to reduce the likelihood that embolic material (see Col. 14, lines 5-33 and in particular, lines 29-31). In the device of claim 4, temperature is sensed to prevent undesirable thermal spread -- in other words, to assist in forming thin lesions without undue damage to surrounding tissue. No tissue clamping device is disclosed in the cited art or, to the best of Applicant's recollection, in any other prior art, that employs a thermocouple to sense the temperature of tissue compressed between the jaws of the clamping device.

Also, convex mating surface (claim 1) or the conductive ablation member and receding clamping surfaces (claim 4) allow the jaws to bring together opposed walls of a vessel or organ, such as opposed walls of the pulmonary trunk, and to compress those surfaces together, expressing from between them most blood or other liquid located between the walls, and allowing direct contact of the opposed vessel walls. This reduces the chance or opportunity for coagulation of liquid located between the walls. Such a feature or benefit of the claimed invention is not disclosed or suggested in the Koblish patent, and is actually contrary to how the Koblish device functions.

Applicant has added independent claim 7 directed specifically to a tissue clamping device having jaw to compress tissue therebetween and at least one thermocouple to sense the temperature of tissue clamped therebetween. For the reason explained in detail above, such a device is not shown or suggested by the prior art.

For these reasons, it is also respectfully submitted that the subject matter of claim 1, 4 and 7 is not disclosed or suggested by the prior art and that claim 1, 4 and 7 and their respective dependent claims should be allowed.

For all of the reasons it is respectfully requested that claims 1-7 be reconsidered and allowed.

Respectfully submitted,

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MARKED UP VERSION OF CLAIMS SHOWING CHANGES

1. (Amended) A device for clamping and ablating cardiac tissue comprising:

a first handle member;

a second handle member;

first and second mating jaw members associated with the first and second handle members, respectively, the jaw members being movable by the handle members between a first open position and a second clamped position in which the jaws are substantially parallel, the jaw members having ~~insulated outer surfaces with~~ convex, opposed and facing mating surfaces, each mating surface having a central peak, the central peak of the first jaw being aligned with the central peak of the second jaw;

a first elongated ~~electrode~~ electrically conductive ablation member extending along the central peak of carried by the first jaw member so as to provide electrical current generally along the central peak to tissue clamped between the jaw members;

a second elongated ~~ablation electrode~~ electrically conductive ablation member extending along the central peak of carried by the second jaw member so as to provide electrical current generally along the central peak to tissue clamped between the jaw members;

the first and second ~~ablation electrodes~~ conductive ablation members being adapted to be connected to an RF energy source ~~so that, when activated, the first and second electrodes are of opposite polarity;~~ and

one of the first and second mating jaw members having at least one thermocouple ~~on its mating surface~~ disposed for measuring the temperature of tissue held between the jaw members, the thermocouple being adapted to be connected to a remote monitoring device.

4. (Amended) A tissue grasping apparatus comprising:

first and second grasping jaws, the grasping jaws being relatively moveable between open and closed positions, the jaws being substantially parallel in the closed position to compress tissue therebetween; each jaw including a ~~raised electrode~~ conductive ablation member and a receding clamping surface in face-to-face relation with the ~~electrode~~ conductive ablation member and receding clamping surface of the other jaw; the clamping surfaces of the jaws comprising an insulating material and the ~~raised~~, face-to-face ~~electrodes~~ conductive ablation members being ~~of opposite polarity~~ and connectible to a power source for providing an electrical current ~~between the electrodes~~ through tissue clamped between the jaws; one of the first and second grasping jaws having at least one thermocouple ~~on its clamping surface~~ disposed for measuring the temperature of tissue held between the grasping jaws, the thermocouple being adapted to be connected to a remote monitoring device.